dividuals being served, taking into account special procedures or precautionary measures which have been or are being instituted.

**§ 405.1306 Time limitations on certification of substantial compliance.**

(a) All initial certifications by the State agency to the effect that an independent laboratory is in substantial compliance with the conditions will be for a period of 1 year, beginning with July 1, 1966, or, if later, with the date on which the laboratory is first found to be in substantial compliance with the conditions. State agencies may visit or resurvey laboratories where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State may, at any time, find and certify to the Secretary that a laboratory is no longer in compliance.

(b) If a laboratory is certified by the State agency as in substantial compliance under the provisions of § 405.1305(b), the following information will be incorporated into the finding and into the notice to the laboratory of the coverage of its services under the medical insurance program:

(1) A statement of the deficiencies which were found, and

(2) A description of progress which has been made and further action which is being taken to remove the deficiencies, and

(3) A scheduled time for a resurvey of the laboratory to be conducted not later than the ninth month (or earlier, depending on the nature of the deficiencies) of the period of certification.

**§ 405.1307 Certification of noncompliance.**

The State agency will certify that a laboratory is not in compliance with the conditions or, where a determination of compliance has been made, that a laboratory is no longer in compliance where:

(a) The laboratory is not in compliance with the statutory requirement of section 1861(s)(10) of the Act; or

(b) The laboratory has deficiencies of such character as to seriously limit the capacity of the laboratory to render adequate service or to place health and safety of individuals in jeopardy, and the State agency concludes after discussion with the laboratory that there is no early prospect of such significant improvement as to establish substantial compliance, or

(c) After a previous period or part thereof for which the laboratory was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served.

**§ 405.1308 Criteria for determining substantial compliance.**

Findings made by a State agency as to whether an independent laboratory is in substantial compliance with the conditions require a thorough evaluation of the laboratory. The State evaluation will take into consideration:

(a) The degree to which each standard, as well as the total set of standards relating to a condition, is met;

(b) When there is a deficiency, whether the deficiency creates a serious hazard to health and safety; and

(c) Whether the laboratory is making reasonable plans and efforts to correct the deficiency within a reasonable period.

**§ 405.1309 Documentation of findings.**

The findings of the State agency with respect to each of the conditions should be adequately documented. Where the State agency certifies to the Secretary that a laboratory is not in compliance with the conditions, such documentation should include a report of any discussions concerning the deficiencies, a report of the laboratory's responses with respect to such discussions, and the State agency's assessment of the prospects for such improvements as to enable the laboratory to achieve substantial compliance with the conditions.

**§ 405.1310 Condition—compliance with State and local laws.**

The laboratory is in conformity with all applicable State and local laws.

(a) *Standard. Licensure.* The laboratory, in any State in which State or applicable local law provides for the licensing of laboratories (1) is licensed pursuant to such law, or (2) is approved, by the agency of the State or locality responsible for licensing laboratories, as meeting the standards established for such licensing.

(b) *Standard. Licensed staff.* The director and the staff of the laboratory are licensed or registered in accordance with applicable laws.

(c) *Standard. Fire and safety.* The laboratory is in conformity with laws relating to fire and safety, and to other relevant matters.

**§ 405.1311 Clinical laboratory; defined.**

A clinical laboratory is an independent laboratory (as previously defined, see § 405.1301) where microbiological, serological, chemical, hematological, biophysical, cytological, immunohematology or pathological examinations are performed on materials derived from the human body, to provide information for the diagnosis, prevention or treatment of a disease or assessment of a medical condition.

**§ 405.1312 Condition—clinical laboratory; laboratory director.**

The clinical laboratory is under the direction of a qualified person.

(a) *Standard. Administration.* The laboratory has a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests. The factors explaining the standard are as follows:

(1) The director serves the laboratory full-time, or on a regular part-time basis. If he serves on a regular part-time basis, (i) he does not individually serve as director of more than two laboratories (hospital or independent) or, (ii) he provides an associate, qualified under the standard in paragraph (b) of this section to serve as assistant director in each laboratory. Such assistant director does not serve more than two laboratories.

(2) Commensurate with the laboratory workload, the director spends an adequate amount of time daily in the laboratory to direct and supervise the technical performance of the staff.

(3) The director is responsible for the proper performance of all tests made in the laboratory.

(4) The director is responsible for the employment of qualified laboratory personnel and their in-service training.

(5) If the director is to be continuously absent for more than 1 month, arrangements are made for a qualified substitute director.

(b) *Standard Laboratory director—qualification.* The laboratory director meets one of the following requirements:

(1) He is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for such certification.

(2) He is a physician who (i) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or (ii) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the laboratory specialties, or (iii) subsequent to graduation has had 4 or more years of general laboratory training and experience of which at least two were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(3) He holds an earned degree of doctor of science or doctor of philosophy from an accredited institution with a chemical, physical, or biological science as his major subject ("accredited," as used herein, refers to accreditation by a nationally recognized accrediting agency or association, as determined by the U.S. Commissioner of Education) and (i) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the laboratory specialties, or (ii) subsequent to graduation, has had 4 or more years of general clinical laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical

laboratory personnel, in a clinical laboratory acceptable to that State.

(4) For the period ending June 30, 1971, an exception to the requirements in subparagraphs (1), (2), or (3) of this paragraph may be made if (i) the director was responsible for the direction of a clinical laboratory on January 1, 1966, and (ii) the State agency has evidence of successful participation of the laboratory which he directs, in a State or State approved proficiency testing program covering the specialties or subspecialties in which the laboratory performs tests, and (iii) the director holds at least a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject and subsequent to graduation has had at least 6 years of pertinent clinical laboratory experience.

**§ 405.1313 Condition—clinical laboratory; supervision.**

The clinical laboratory is supervised by qualified personnel.

(a) *Standard. Supervision.* The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures. The factors explaining the standard are as follows:

(1) Depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

(2) The supervisor serves the laboratory on a regular full-time basis.

(3) The supervisor supervises and performs tests only in those laboratory specialties or subspecialties in which he is qualified by education, training, and experience.

(b) *Standard. Supervisor—qualification.* The laboratory supervisor meets one of the following requirements:

(1) He (i) is a physician or has earned a doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject, and (ii) subsequent to graduation has had at least 2 years' experience in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(2) He holds a degree of master of arts or master of science from an accredited institution with a major in one of the chemical, physical, or biological sciences and subsequent to graduation, has had at least 4 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(3) He holds a degree of bachelor of arts or bachelor of science from an accredited institution with a major in one of the chemical, physical, or biological sciences, and, subsequent to graduation (i) has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; and (ii) has successfully completed pertinent courses in an accredited college or university which, when combined with the foregoing experience, will provide technical and professional knowledge comparable to that of subparagraph (2) of this paragraph.

(4) He is registered as a clinical laboratory technologist by the American Society of Clinical Pathologists, MT (ASCP), the National Registry of Microbiologists, or other professionally sponsored national registry acceptable to the Secretary which maintains standards equivalent to the foregoing, and (i) has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, university, health department, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; and (ii) has successfully completed pertinent courses in an accredited college or university which, when combined with the foregoing experience, will provide a technical and professional knowledge comparable to that of subparagraph (2) of this paragraph.

**§ 405.1314 Condition—clinical laboratory; tests performed.**

The clinical laboratory performs only those laboratory tests and procedures that are within the specialties in which the laboratory director or supervisors are qualified.

(a) *Standard. Procedures and tests—competency.* The laboratory performs only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified. The factors explaining the standard are as follows:

(1) If the laboratory director or supervisor is a pathologist certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification, the laboratory may perform laboratory procedures and tests in all specialties.

(2) If neither the director nor supervisor has the qualifications described in subparagraph (1) of this paragraph and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, serology, virology, mycology and parasitology, the laboratory engages the services of a qualified director or supervisor, as defined previously, who (i) holds an earned doctoral or master's degree in microbiology from an accredited institution or is a physician and (ii) subsequent to graduation has had at least 4 years' experience in clinical microbiology.

(3) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of immunohematology, including the subspecialties of blood groupings and RH typing, it engages the services of a qualified director or supervisor, as defined previously, who is a physician with at least 2 years' experience in clinical hematology subsequent to graduation.

(4) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of hematology, including gross and microscopic examination of the blood, it employs a qualified director or supervisor, as defined previously, who holds a master's or bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 4 years' experience in hematology.

(5) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of clinical chemistry, it engages the services of a qualified director or supervisor, as defined previously, who (i) holds an earned doctoral or master's degree in chemistry or biochemistry from an accredited institution or is a physician, and (ii) subsequent to graduation has had at least 4 years' experience in clinical chemistry.

(6) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of tissue pathology, it engages the services of a pathologist who is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification.

(7) If the factor in subparagraph (1) of this paragraph is not met and the laboratory performs tests in the specialty of exfoliative cytology, it engages the services of a physician who: (i) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology, or possesses qualifications which are equivalent to those required for certification or (ii) is a member of the American Society of Cytology.

(8) The laboratory whose director qualifies under § 405.1312(b)(4), may perform tests in the laboratory specialties in which such director is specifically qualified by training and experience. It performs tests in other laboratory specialties only if the director or supervisor meets the appropriate requirements of subparagraphs (1)–(7) of this paragraph.

**§ 405.1315 Condition—clinical laboratory; technical personnel.**

The clinical laboratory has a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

(a) *Standard. Technologist—duties.* The laboratory employs a sufficient number of clinical laboratory technologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment. The factors explaining the standard are as follows:

(1) The clinical laboratory technologists perform tests which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisors, in only those specialties or subspecialties in which they are qualified by education, training, and experience.

(2) With respect to specialties in which the clinical laboratory technologist is not qualified by education, training, or experience, he functions only under direct supervision and performs only tests which require limited technical skill and responsibility.

(3) Clinical laboratory technologists are in sufficient number to adequately supervise the work of technicians and trainees.

(b) *Standard. Technologists—qualifications.* Each clinical laboratory technologist possesses a current license as a clinical laboratory technologist issued by the State, if such licensing exists, and meets one of the following requirements:

(1) He holds a degree of bachelor of arts or bachelor of science from an accredited institution with a major in one of the chemical, physical, or biological sciences and (i) has been employed for at least 1 year as a clinical laboratory technician or trainee in a clinical laboratory—with a director at the doctoral level—of a hospital, health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; or (ii) has successfully completed at least 1 year of clinical laboratory internship as part of his college curriculum.

(2) He is registered by (i) the American Society of Clinical Pathologists as a medical technologist, MT(ASCP), or as a clinical laboratory specialist or, (ii) the National Registry of Microbiologists or, (iii) other professionally sponsored national registry acceptable to the Secretary which maintains standards equivalent to (i) and (ii) above.

(c) *Standard. Technician—duties.* Clinical laboratory technicians are employed in sufficient number to meet the workload demands of the laboratory and they function only under direct supervision of a clinical laboratory technologist. The factors explaining the standard are as follows:

(1) Each clinical laboratory technician performs only those laboratory procedures which require limited technical skill and responsibility and a minimal exercise of independent judgment.

(2) No one with lesser qualifications than a clinical laboratory technician performs laboratory procedures, although manual and clerical supplemental services may be rendered by others.

(3) No clinical laboratory technician performs tests in the absence of a clinical laboratory technologist.

(d) *Standard. Technician—qualifications.* Each clinical laboratory technician possesses a current license as a clinical laboratory technician issued by the State, if such licensing exists, and meets one of the following requirements:

(1) He has successfully completed 60 semester hours in an accredited college including the following courses: general chemistry, 1 year; biology or microbiology, 1 year.

(2) He is a high school graduate and subsequent to graduation has served 2 years as a technician trainee in a clinical laboratory with a director at the doctoral level or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

(e) *Standard. Collection of specimens.* No person other than a licensed physician or one otherwise authorized by law manipulates a patient for the collection of specimens except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction or upon the written request of a licensed physician.

(f) *Standard. Personnel policies.* There are written personnel policies, practices, and procedures that adequately support sound laboratory practice. The factors explaining the standard are as follows:

(1) Current employee records are maintained and include a résumé of each employee's training and experience.

(2) Files contain evidence of adequate health supervision of employees, such as results of preemployment and periodic physical examinations, including chest X-rays, and records of all illnesses and accidents occurring on duty.

(3) Work assignments are consistent with qualifications.

(4) There is a program for employee orientation.

**§ 405.1316 Condition—clinical laboratory; records, equipment, and facilities.**

The clinical laboratory maintains records, equipment, and facilities which are adequate and appropriate for the services offered.

(a) *Standard. Laboratory management.* Space, facilities, and equipment are adequate to properly perform the services offered by the laboratory. The factors explaining the standard are as follows:

(1) There is an adequate quality control program in effect including the use, where applicable, of reference or control sera and other biological samples, concurrent calibrating standards, and control charts recording standard readings.

(2) All equipment is in good working order, routinely checked and precise in terms of calibration.

(3) Workbench space is ample, well-lighted and convenient to sink, water, gas, suction and electrical outlets as necessary.

(4) The laboratory is properly ventilated.

(5) Notebooks of appropriate current laboratory methods are available.

(6) Adequate fire precautions are observed.

(7) There is freedom from unnecessary physical, chemical, and biological hazards.

(b) *Standard. Sterilization.* Syringes, needles, lancets or other blood letting devices capable of transmitting infection from one person to another are not reused unless they are sterilized prior to each use after first having been wrapped or covered in a manner which will insure that they remain sterile until the next use. The factor explaining the standard is as follows:

Each sterilizing cycle contains an indicator device which assures proper sterilization.

(c) *Standard. Examination and reports.* The laboratory examines specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and reports only to those authorized by law to receive such results. The factors explaining the standard are as follows:

(1) If the patient is sent to the laboratory, a written request for the desired laboratory procedures is obtained from a person authorized by law to use findings of laboratory examinations.

(2) If only a specimen is sent, it is accompanied by a written request.

(3) If the laboratory receives reference specimens from another laboratory, it may report back to the laboratory submitting the specimens.

(d) *Standard. Specimens— records.* The laboratory maintains a record indicating the daily accession of specimens each of which is numbered or otherwise appropriately identified. The factor explaining the standard is as follows:

Records contain the following information:

(1) The laboratory number or other identification of the specimen.

(2) The name and other identification of the person from whom the specimen was taken.

(3) The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen.

(4) The date the specimen was collected by the physician or other authorized person.

(5) The date the specimen was received in the laboratory.

(6) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed or turbid, etc.).

(7) The type of test performed.

(8) The result of the laboratory test or cross reference to results and the date of reporting.

(e) *Standard. Laboratory report and record.* The original laboratory report is sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result is preserved by the laboratory in accordance with the State's statutes of limitations. The factors explaining the standard are as follows:

(1) The laboratory director is responsible for the laboratory report.

(2) Duplicate copies or a suitable record of laboratory reports are filed in the laboratory in a manner which permits ready identification and accessibility.

(3) Tissue pathology reports utilize acceptable terminology of a recognized system of disease nomenclature.

(4) The results of laboratory tests or procedures or transcript thereof are not sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

**§ 405.1317 Radiology and/or nuclear medical isotope laboratories; defined.**

A radiology and/or nuclear medical isotope laboratory is any independent laboratory (as previously defined, see § 405.1301) where ionizing radiation is used for diagnostic purposes. The term nuclear medical isotope laboratory refers to laboratories in which radioactive isotopes are applied to, injected in, or ingested by patients for diagnostic purposes.

**§ 405.1318 Condition—radiology and/or nuclear medical isotope laboratory; direction of laboratory and interpretation of procedures.**

The radiology and/or nuclear medical isotope laboratory is directed by a qualified physician and provides for the interpretation of procedure results.

(a) *Standard. Administration.* The laboratory has a director who administers the technical and scientific operation of the laboratory. The factors explaining the standard are as follows:

(1) The director serves the laboratory fulltime, or he may serve the laboratory on a regular part-time basis. If he serves on a regular part-time basis, (i) he does not individually serve as director of more than two laboratories or, (ii) he provides a qualified associate to serve as assistant director in each laboratory. Such assistant director does not serve more than two laboratories.

(2) The director is responsible for assuring that all roentgenologic and/or radioisotope procedures are properly performed and that the operation of radiographic equipment and use of radioactive materials are limited to qualified personnel.

(3) The director spends an adequate amount of time each week in the laboratory to direct and supervise the technical performance of the staff.

(4) If the director is not fulltime, or if the size of staff makes it necessary, the director designates a supervisor whom he deems qualified for this position to supervise laboratory personnel and perform procedures requiring special skills. The supervisor works under the general direction of the director.

(5) The director is ultimately responsible for the employment of personnel who are qualified for the positions for which they are hired and for assuring that they comply with applicable Federal and State standards pertaining to personnel who conduct procedures involving the use of ionizing radiation for diagnostic purposes.

(6) If the director is to be continuously absent for more than 1 month, arrangements are made for a qualified substitute director.

(b) *Standard. Director — qualification.* The director is a physician licensed to practice medicine in the State and is qualified by training and experience in the use of X-rays and/or radioactive materials for diagnostic purposes.

(c) *Standard. Technologists and associated personnel.* The number of radiologic and/or nuclear medical technologists and associated personnel employed as well as their training and experience, is adequate for the workload, considering the complexities of the radiologic procedures and the amount of time necessary for their execution. The factor explaining the standard is as follows:

Technologists employed by the laboratory are certified by the American Registry of Radiologic Technologists, or registered by the Registry of Medical Technologists (ASCP) as nuclear medical technologists, or meet equivalent requirements.

(d) *Standard. Interpretation of procedures.* The laboratory provides for the interpretation of the results of each roentgenological and/or radioisotope procedure. This interpretation is made by a physician qualified in the field. The factor explaining the standard is as follows:

The interpretation of the results of each procedure is made only by a physician who is licensed to practice medicine in that State and i...s the appropriate specialized knowledge needed to arrive at the interpretation.

(e) *Standard. Fluoroscopic examinations.* Fluoroscopic examinations of patients are performed only by physicians whose training and experience are adequate to interpret the findings of the procedure. The factor explaining the standard is as follows:

Fluoroscopic procedures are not conducted by technologists.

(f) *Standard. Report of diagnostic procedure.* A signed report is made by a physician qualified in the field for each diagnostic roentgenologic and/or isotope procedure, and is transmitted to the referring physician. Records are maintained of all such reports. The factors explaining the standard are as follows:

(1) Records contain a concise statement of the referring physician's reason for requesting the procedure.

(2) Copies of reports and radiographs are preserved or microfilmed in accordance with the State's statutes of limitations.

(g) *Standard. Personnel policies.* There are written personnel policies, practices, and procedures that adequately support sound laboratory practice. The factors explaining the standard are as follows:

(1) Current employee records are maintained and include a résumé of each employee's training and experience.

(2) Files contain evidence of adequate health supervision of employees such as results of preemployment and periodic physical examinations, including chest X-rays, and records of all illnesses and accidents occurring on duty.

(3) Work assignments are consistent with qualifications.

(4) There is a program for employee orientation.

**§ 405.1319 Condition—radiology and/or nuclear medical isotope laboratory; standards for safety.**

The laboratory meets professionally approved standards for safety.

*Standard. Safety program.* There is in effect a strict control program to reduce radiation and other hazards associated with the technical operations of the laboratory. The factors explaining the standards are as follows:

(a) Proper safety precautions are maintained against fire and explosion hazards, electrical hazards, and radiation hazards.

(b) Periodic inspections are made by local or State health authorities, or by other qualified individuals, and hazards so identified are promptly corrected. Records are maintained of such current inspections.

(c) Personnel monitoring is used for those radiation workers whose exposures are likely to exceed 25 mR per week.

(d) Radiation barriers and shielding are adequate to limit radiation exposures of personnel and the environs within acceptable limits.

(e) Restrictions of X-ray beam size is attained through proper and regular use of the appropriate limiting cone or the proper setting of the variable aperture collimator in radiographic procedures.

(f) Appropriate filtration of the X-ray beam is used.

(g) Only shockproof equipment is used.

(h) All electrical equipment is grounded.

(i) With fluoroscopes, attention is paid to modern safety design and good operating procedures; records are maintained of the exposure rate at the panel or table top of all fluoroscopes.

(j) Radioactive materials are stored and used in accordance with the provisions of applicable Federal or State standards and conditions of licensure.

(k) The space and equipment are adequate for the volume and diversity of procedures done by the laboratory.

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